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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/633,295	08/07/2000	Alfons Nichtl	100564-00025	4590

7590

03/15/2002

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EXAMINER

DO, PENSEE T

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 03/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/633,295

Applicant(s)

NIGHTL, ALFONS

Examiner

Pensee T. Do

Art Unit

1641

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 15 February 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☒ they raise the issue of new matter (see Note below);
 - (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.
- NOTE: see attachment.
3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 24-39.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____.

ADVISORY ACTION

Amendment Entry and Pending Claims

1. The after-final amendment filed on February 15, 2002 will not be entered because applicants have incorporated a new limitation which would require a new search.
2. Claims 24-39 are pending.

MAINTAINED REJECTION(S)

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 24, 30, 31 and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Liberti et al. (US 5,597,531).

Liberti teaches a coating process comprising coating a wide range of materials (including dextran, proteins, synthetic polypeptides, polymers, detergents, polyethylene glycol and combinations thereof) onto colloidal magnetically responsive particles to obtain stable microagglomerants. The process comprises the following steps:

- (a) forming a liquid mixture of a particulate magnetic starting material and a coating material;

- (b) treating the mixture to subdivide the particles of the magnetic starting material;

- (c) permitting the coating material to form a coating on the subdivided particles of the magnetic starting material to form stable, resuspendable coated particles;

- (d) recovering the resuspended coated magnetic particles from the liquid mixture. (See col. 4, lines 45-52; claim 1).

Claims 24, 29-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Olsen (US 5,393,658).

Olsen teaches an immunoassay wherein suspected microorganisms (biomolecules) are treated with a detergent solution to expose additional reactive epitopes of the biomolecule. The detergent treated microorganisms are reacted with specific colloidal gold labeled antibodies directed against specific antigens of

the suspected organism being identified. (see col. 2, lines 25-33). Amphoteric (zwitterionic) and nonionic detergents in concentrations ranging from 0.01% to 5% have been found to be useful to perform optimally in extracting membrane antigens and exhibiting minimal interference of the progression of the antibody antigen reaction. (see col. 2, lines 58-70).

Claim Rejections - 35 U.S.C. § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 25-29, 32, 34-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liberti et al. (US 5,597,531) further in view of Nichtl et al. (US 5,972,720).

Liberti teaches a coating process comprising coating a wide range of materials (including dextran, proteins, synthetic polypeptides, polymers, detergents, polyethylene glycol and combinations thereof) onto colloidal magnetically responsive particles to obtain stable microagglomerants. The process comprises the following steps:

(a) forming a liquid mixture of a particulate magnetic starting material and a coating material;

(b) treating the mixture to subdivide the particles of the magnetic starting material;

(c) permitting the coating material to form a coating on the subdivided particles of the magnetic starting material to form stable, resuspendable coated particles;

(d) recovering the resuspended coated magnetic particles from the liquid mixture. (See col. 4, lines 45-52; claim 1).

Liberti also fails to teach an additional stabilizer such as an inert protein or/and polyethylene glycol after loading the colloidal particles and colloidal particles selected from the group consisting of gold, silver, copper, platinum, palladium and mixture thereof.

Nichtl teaches that after the colloidal particles have been loaded with the respective desired biomolecule, it is necessary to stabilize the conjugates. This stabilization minimizes an aggregation of the particles and to saturate the remaining free surfaces accessible to adsorption. In the state of the art inert proteins, e.g. bovine serum albumin, detergents, and polymers such as polyethylene glycol, polyvinylpyrrolidone, polyvinyl alcohol, polyvinyl sulfate, dextran and gelatin are used as stabilizers. Nichtl also teaches a new stabilizer, thiol-substituted polyethylene glycol, which is added to the conjugate of gold particles or metallic particles such as particles of metals, metal oxides, metal hydroxides, metal compounds or particles coated with metals or metal compounds. The metal particles are selected from the group consisting of gold,

silver, copper, platinum, palladium, and mixture thereof. (see col. 1, lines 47-61; col. 2, lines 25-28; col. 2, line 53-col. 3, line 7).

It would have been obvious to one of ordinary skills in the art to add the an inert protein selected among those taught in Nichtl to the conjugate formed by the method of Liberti since Liberti and Nichtl both teach improving the long-term stability of the conjugates and lowering the aggregation or agglomeration tendency in solution. (see Nichtl col. 2, lines 25-36).

Response to Arguments

Applicant's arguments filed on February 15, 2002 have been fully considered but they are not persuasive.

Applicants' arguments are based upon the amended claims which will not be entered. Thus, no further discussion is necessary.

Applicants also mentioned that the assumption in the office action that adding a detergent would cause the same effect as mechanical disintegration of the agglomerates has no foundation whatsoever. Mechanical disintegration of agglomerates leads to new surfaces being formed which then can be coated by a detergent. However, a detergent cannot form said new surfaces itself.

First of all, mechanical disintegration of agglomerates was not recited in the claims. The claims simply recite a method of stabilizing conjugates composed of colloidal particles and biomolecules, the method comprising the steps of :

- adding a detergent to a solution containing biomolecules; and
thereafter

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- loading colloidal particles with the solution;

Thus, if the prior arts teaches all of the above steps and materials, the results would be the same as the claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 703-308-4398. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-746-5291 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Pensee T. Do
Patent Examiner
March 14, 2002



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800-1641